REMARKS

Claims 47-53 and 58-59 are now pending. The Applicant herein respectfully requests further examination of the application and reconsideration of the rejections, in view of the amendments and following remarks.

The Applicant respectfully points out that the current Judicial interpretation of the requirement for written description under Title 35 USC §112, paragraph 1, is that all functional descriptions of genetic material do not necessarily fail as a matter of law to meet the requirement; rather, the written description may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.

"The written description requirement does not require the applicant to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Moba v. Diamond, United States Court of Appeals for the Federal Circuit, 01-1063, -1083, Decided April 1, 2003.

The seminal Federal Circuit case Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) invoked the written description requirement requiring a precise definition of a DNA sequence in the patent specification. In more recent cases, however, the Federal Circuit has distinguished Lilly in its interpretation of the statutory requirement for written description. For instance, in Enzo Biochem, Inc. v. Gen-Probe, Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002), neither the specification nor the deposited biological material recited the precise "structure, formula, chemical name, or physical properties" required by Lilly. Id. at 1324 (quoting Lilly, 119 F.3d at 1566). Although the court initially determined that the specification in Enzo did not satisfy the Lilly disclosure rule, it revisited the issue and remanded to the district court. The court instructed: "[o]n remand the court should determine whether a person of skill in the art would glean from the written description, including information obtainable from the deposits of the claimed sequences, subsequences, mutated variants and mixtures sufficient to demonstrate possession of the generic scope of the claims." Enzo, 296 F.3d at 1328. Similarly, in the Federal Circuit's most recent pronouncement, it noted: "[m]ore recently, in Enzo Biochem, we clarified that Eli Lilly did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge

of the art the disclosed function is sufficiently correlated to a particular, known structure." Amgen Inc. v. Hoechst Marion Roussel Inc., 314 F.3d 1313, 1332, 65 USPQ2d 1385 (Fed. Cir. 2003).

Similarly, in the facts of the instant case, the Lilly disclosure rule does not require a particular form of disclosure because one of skill could determine from the specification that the inventor possessed the invention at the time of filing. Particularly, claims 47-53, 58 and 59 are now amended to replace the language "[a] nucleotide sequence which is of sufficient length to regulate the level of ACC synthase gene expression" with "[a]n isolated nucleotide sequence which is of sufficient complementarity to an endogenous ACC synthase gene to reduce expression of said endogenous ACC synthase gene". The claims are now drawn to an isolated nucleic acid that has sufficient complementarity to an endogenous ACC synthase to reduce expression of that endogenous ACC synthase. The Applicant respectfully submits that the specification indeed provides more than adequate support for the subject matter of the claims now presented. Support for this amendment can be found in the specification as filed at page 11, line 23 to page 12, line 5, which describes methods for RNA-mediated suppression (both sense and antisense) of endogenous genes, techniques which are conventional in the art and known to those of ordinary skill in the art. Complementarity of DNA and RNA sequences and hybridization techniques are also discussed in length in the specification at page 4, line 27 to page 8 line 27.

The patent specification must disclose information sufficient to enable those skilled in the art to make and use the claimed invention; however, the fact that some experimentation is required to practice the claimed invention is permissible, *so long as it is not undue.* Atlas Powder Co. v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984)

The Applicant respectfully submits that determination of the level of sequence complementarity required to suppress endogenous ACC synthase gene expression is not an unpredictable art (Blokland *et al.*; Bourke J., page 126, column 1; *see* attached documents). The amended claims are directed to nucleic acid sequences with high sequence similarity to SEQ ID NOS: 1 and 5. Hence there is a high probability that sequences hybridized under stringency conditions (i) and (ii) would be of sufficient complementarity to reduce expression of an endogenous ACC synthase gene. Any additional experimentation by a skilled person to

determine which sequences have sufficient complementarity would be minimal or non existent. Therefore, those of ordinary skill in the art could readily make and use the nucleotide sequences as per claims 47-53, 58 and 59 without undue experimentation.

The Applicant respectfully requests the Examiner to withdraw the rejection to the claims under 35 USC §112, paragraph 1.

Non-statutory double patenting rejection

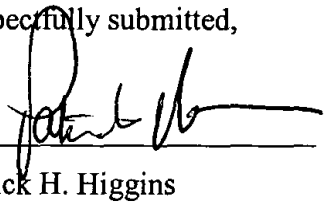
The applicant respectfully includes herewith a terminal disclaimer under 37 CFR 1.321(c), to obviate the rejection.

* * *

For all the foregoing reasons, the applicant submits that Claims 47-53 and 58-59 are in condition for allowance. Early action toward this end is courteously solicited. *The Examiner is kindly encouraged to telephone the undersigned in order to expedite any detail of the prosecution*.

A check in the amount of $110.00 to cover the cost of the one-month extension is enclosed. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,



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